CE

QwikCheck™ Gold

Sperm Quality Analyzer

USER GUIDE

WHO 5th Version

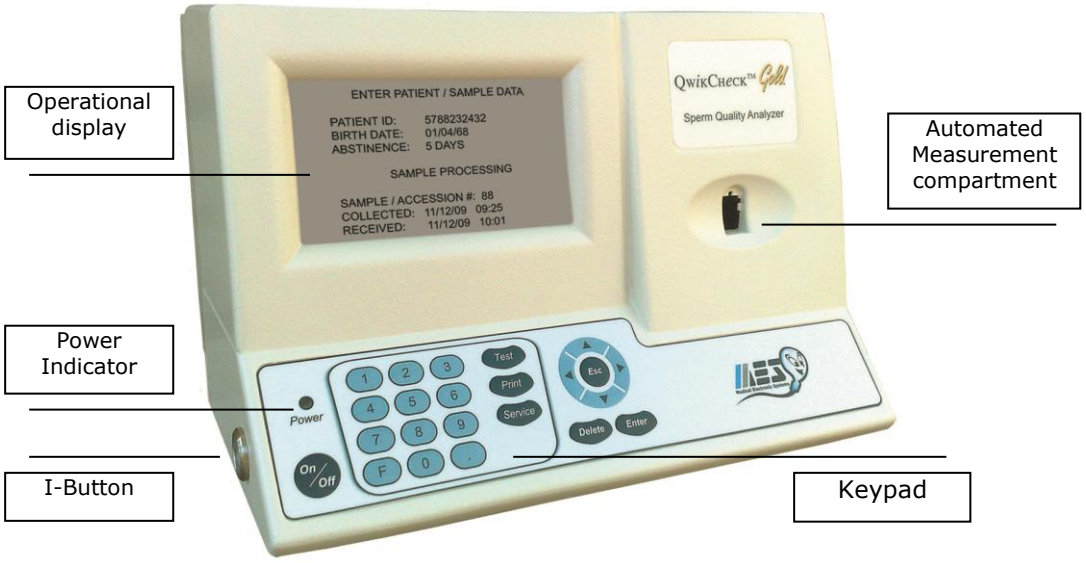
Version 1.00

February 2022

Table of Contents

SECTION 1: System Overview

The QwikCheck™ Gold is a high performance, menu driven analytical medical device for assessing human semen. The combination of technology in electro-optics and computer algorithms results in a precise and accurate 75-second semen analysis. The system is self-testing and self-calibrating and runs latex beads or stabilized sperm quality controls.



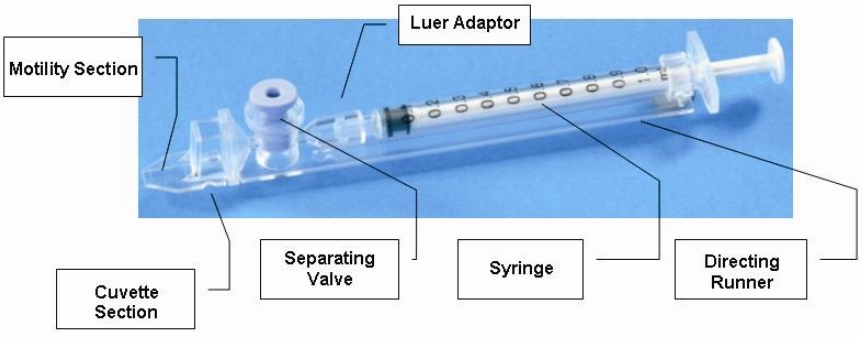
QwikCheck™ Gold **Keypad**

Keypad Navigation

- Use **NUMERIC** keys to enter data; **ARROW** keys to move to the next field.
- Press **ENTER** to select menu options, confirm data entries and to move to the next screen or field.
- Use the **ESC** button to return to the previous screen or field.

Testing Capillary

QwikCheck™ Gold **Testing Capillary**



- Disposable, designed to collect and test samples in a biologically safe manner.
- Motility is measured in the 0.3 mm (thin) "Capillary Section." This section requires 20 micro liters of semen.
- Concentration is measured in the 10 mm (tall) "Cuvette Section." This section requires 450 microliters of semen.

Automated Test Results

Semen Parameters Reported by the QwikCheck™ Gold

Semen Parameters with QwikCheck GOLD Abbreviation in Brackets			
Sperm Concentration (SPERM CONC.)	M/ml	Velocity (VELOCITY)	mic /sec
Total Motility (TOTAL MOTILITY <PR+NP)	%	Sperm Motility Index (SMI)	#
Progressive Motility (PROG. MOTILITY <PR>)	%	Total Sperm Number / ejaculate (SPERM #)	M
Non-progressive Motility (NONPROG. MOTILITY <NP>)	%	Total Motile Sperm / ejaculate (MOT. SPERM)	M
Immotility (IMMOTILTIY <IM>)	%	Progressively Motile Sperm Concentration (PMSC)	M/ml
Sperm Morphology (normal forms, %)(MORPH. NORM. FORMS, WHO 5th)	%	Total Progressively Motile Sperm / ejaculate (PROG. SPERM)	M
Motile Sperm Concentration (MSC)	M/ml	Functional Sperm Concentration: Progressively Motile Sperm with normal Morphology (FSC)	M/ml
Total Morphologically Normal Sperm / ejaculate (MORPH. NORM. SPERM)	M	Total Functional Sperm / ejaculate (FUNC. SPERM)	M

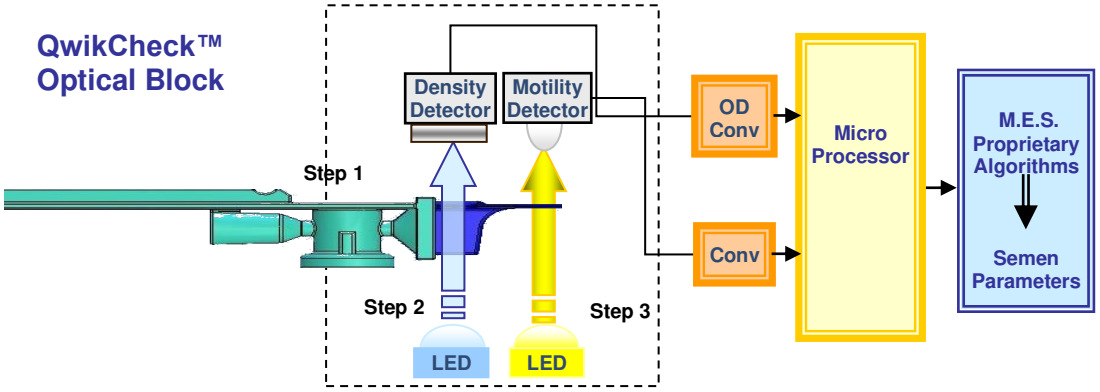
Dynamic Range

Table of the Dynamic Range of the QwikCheck™ Gold

DYNAMIC RANGE OF THE SYSTEM Gold			
SAMPLE	**SPERM CONC in M/ml**	**MSC in M/ml**	**Motility %**
FRESH	2-400 or < 2 M/ml	0.2-400 or <0.2 M/ml	0-100%
WASHED	2-200 or < 2 M/ml	0.2-200 or <0.2 M/ml	0-100%
FROZEN	Not reported	0.2-200 or <0.2 M/ml	Not reported

Technology

SECTION 2: Technology



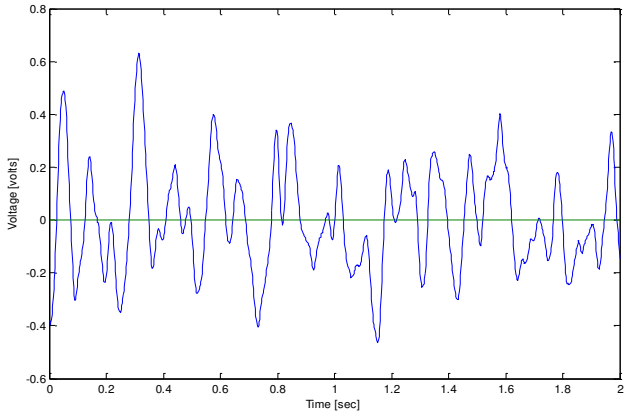
Step 1: **The capillary is inserted into the measurement compartment.**

Step 2: **Concentration:**

- Millions of sperm cells are analyzed: A very specific wavelength of light is absorbed by the sperm cells in the concentration chamber of the testing capillary.
- An detector measures the amount of light absorbed by the cells and converts it to optical density (OD).
- The "OD" reading is translated into sperm concentration by a microprocessor based on proprietary algorithms.

Step 3: **Motility:**

- Tens of thousands of sperm cells are analyzed in the thin section of the testing capillary as they move through a light beam in the system, causing light disturbances.
- These light disturbances are converted into electronic signals with "peaks and valleys."
- The electronic signal peaks are analyzed by microprocessor software based on a proprietary MES algorithm and translated into motility parameters.



Electronic Signal of Motile Sperm

SECTION 3: Getting Started / Set-Up

Power-On

NOTE:

The QwikCheck GOLD is loaded with a minimal number of I-Button tests in memory. However, the user must load tests right away to ensure that testing will not be interrupted. Please refer to the I-Button loading section of this manual for instructions!

- Plug the system into a grounded electrical source.
- Turn the system on by pressing the main switch located on the rear panel. The **Power** indicator will illuminate and the following screen will be displayed.

```
QwikCheck GOLD
SPERM QUALITY ANALYZER
VERSION 1.0

PRESS ON/OFF KEY
TO ACTIVATE THE UNIT
```

Auto-Calibration and Self-Test

```
QwikCheck GOLD
SPERM QUALITY ANALYZER

PLEASE WAIT
SYSTEM STABILIZATION AND
AUTOCALIBRATION
```

NOTE:

Do not use any of the keyboard functions during stabilization.

- Press **ON/OFF** key on the keypad and auto-calibration will begin (this takes between 5-7 minutes).
- When the calibration is complete, a series of tests will be run.
- Do not insert a capillary into the device or use any of the keyboard functions until instructed to do so by the system.
- The MAIN menu will appear when the self-test process is complete. The system is now ready for use.

```
MAIN MENU

TEST NEW PATIENT
RUN CONTROLS
ADD I-BUTTON TESTS
SERVICE
```

Set-up System Defaults

- Before running a test for the first time, set up the system defaults by going to: **MAIN MENU > SERVICE > SET-UP**

```
SERVICE MENU

SERVICE DATA
SET UP
SERVICE PERSONNEL
PRINT SELF-TEST DATA & SETTINGS
```

- Select either SYSTEM DEFAULTS or CONTROLS when the screen below appears:

```
SERVICE: SET-UP
SELECT:
1. SYSTEM DEFAULTS
2. CONTROLS
SELECT AND PRESS ENTER
```

- **SYSTEM DEFAULTS**: Select the desired date/time formats, label printing preference and concentration standard (see Appendix #12 for a table of counting chambers: NEUBAUER vs. MAKLER type) when the screen below is displayed.

- Press ENTER to accept.

```
SYSTEM DEFAULT SETTINGS
DATE FORMAT: MM/DD/YY / DD/MM/YY
DATE/TIME SETTING: 01/04/05 08:15:45
AUTO PRINTING: YES/NO
# LABELS TO PRINT: 1 / 2
CONC. STD: 1 / 2
```

- **CONTROLS**: Follow the screen prompts and enter the appropriate information from the control (Latex beads or Stabilized Sperm) product labeling.

```
SERVICE: SET-UP CONTROLS
SELECT: LATEX BEADS/STABILIZED
SPERM
SELECT: LEVEL 1 / LEVEL 2 / NEGATIVE

PRESS ENTER TO CONTINUE
ESC TO RETURN TO SERVICE MENU
```

```
SET-UP: LATEX BEADS
LEVEL 1
LOT #: 0013122009
EXP DATE: 12/03/2010
TARGET VALUE: 46 +/- 6.4
PRESS ENTER
```

- Select the type of controls to be run (Latex Beads/Stabilized Sperm)
- Select the LEVEL (1, 2, or NEGATIVE)
- Enter the LOT #/ EXPIRATION DATE and TARGET VALUE from the product labeling.

The **QwikCheck™ Gold** is now ready to test samples and controls!

Testing Samples

SECTION 4: Test New Patient: FRESH, WASHED and FROZEN samples are all run following similar screen instructions. Once the sample type is selected, the menu will direct how to run the sample and what volume is required. If the sample is low quality, the system will perform an additional 2 minute test.

Patient Information

- From the **MAIN MENU** select **TEST NEW PATIENT** and the **ENTER PATIENT/ SAMPLE DATA** screen is displayed.

ENTER PATIENT / SAMPLE DATA	
PATIENT ID:	5788114
BIRTH DATE:	01/01/85
ABSTINENCE:	4 DAYS
SAMPLE / ACCESSION #	58888
COLLECTED: DD/MM/YY	HH:MM
RECEIVED: DD/MM/YY	HH:MM

- Enter the requested sample/patient information using the keypad:
  - **PATIENT ID** – patient identifying #(Maximum 20 numbers can be entered).
  - **BIRTH DATE** – Birth date of the patient.
  - **ABSTINENCE** - Number of days since the patient's last ejaculation.
  - **SAMPLE/ACCESSION #** - Up to 20 numbers identifying the sample
  - **COLLECTED –** Date and time the sample was collected.
  - **RECEIVED –** Date and time the sample was received.

Press **ENTER** to view the next screen:

ENTER SAMPLE DATA	
SELECT	FRESH / WASHED / FROZEN
VOLUME	2.5 ml
WBC CONC.	**SELECT** < 1 M/ml / >= 1 M/ml
PH	7.0

PLEASE NOTE:

The QwikCheck is calibrated to run semen specimens at room temperature. It is not necessary nor will the user get accurate motility results if the sample is heated to 37ºC.

Sample Information

Sample Data

- Select: **SAMPLE TYPE** based on the following options:
  - **FRESH** – Sample not enriched, diluted or treated and is within 1 hour of collection. Exception: Low volume samples diluted 1:1 with QwikCheck dilution media can be used according to User Guide instructions.
  - **WASHED** – Sample enriched or prepared for artificial insemination using a commercial media to replace seminal plasma. Frozen samples containing egg yolk buffer are excluded.
  - **FROZEN** – Samples that have been frozen. Only motility parameters will be reported (MSC, PMSC, SMI and VELOCITY).

PLEASE NOTE:

Refer to the appendix section of this user guide for information on how to measure semen WBC's and pH and how to handle viscous samples.

- Enter the remaining sample information:
  - **VOLUME –** Volume of the whole ejaculate in milliliters
  - **WBC CONC. –** select < 1 M/ml (normal) or >=1 M/ml (abnormal) leukocytes (required entry). (QwickCheck Test Strips recommended).
  - **PH** – pH of the semen sample (QwickCheck Test Strips recommended).

Sample Volume

IS SAMPLE VOLUME SUFFICIENT FOR COMPLETE TESTING >= .5 ml?

YES/NO

- After entering the patient and sample data, the screen above will be displayed.
  - **SELECT: YES** for **NORMAL VOLUME** samples ≥0.5 ml.
  - **SELECT: NO** for **LOW VOLUME** samples < 0.5 ml.

Normal Volume Samples

If **YES:** The sample is ≥0.5 ml the screen below provides instructions for PREPARING a testing capillary. Do not touch the system at this time as it is calibrating for the testing cycle.

NORMAL VOLUME SPECIMEN

FILL, CLEAN & WIPE CAPILLARY

AUTOCALIBRATION-DO NOT TOUCH UNIT

- Fill the testing capillary according to the instructions in the Appendix section of this user guide: "Filling the SQA Capillary with a Normal Volume Sample".
- Insert the testing capillary into the measurement chamber of the QwikCheck GOLD when instructed by the screen below:

NORMAL VOLUME SPECIMEN

FILL, CLEAN & WIPE CAPILLARY

INSERT IN CHAMBER

TESTING

DO NOT MOVE CAPILLARY OR OPERATE DEVICE DURING TESTING

PLEASE NOTE:

The QwikCheck will begin testing when a capillary is placed into the testing chamber.

- Testing will begin automatically – do not touch the system or capillary during testing.
- Test results will be displayed when finished:

TEST RESULTS

SPERM CONC.	32.6 M/ml
TOTAL MOTILITY <PR+NP>	28.0 %
PROG. MOTILITY <PR>	5.2 %
NON PROG. MOTILITY <NP>	8.7 %
IMMOTILITY <IM>	72.0 %
MORPH.NORM.FORMS,WHO 5TH	20.6 %

TEST RESULTS

MSC	9.1 M/ml	FSC	3.2 M/ml
PMSC	5.2 M/ml	VELOCITY	20mic/sec
SMI	72		

TOTALS PER VOLUME

SPERM #	65.2M	MOT. SPERM	18.2M
PROG.SPERM	10.4M	FUNC SPERM	6.4M
MORPH. NORM. SPERM	4.8M		

Low Volume Samples

If the sample is < 0.5 ml two options are available: DILUTE the sample 1:1 (QwikCheck Dilution medial) to obtain a full report or run a LOW VOLUME sample (reports motility parameters only).

Diluted Samples

Recommendation for sample dilution media:

Use **QwikCheck™ Dilution Media** for best results and if the sample is viscous, FIRST treat with **QwikCheck-Liquefaction kit**, then dilute.

To run a **LOW VOLUME DILUTED** sample, select option "1" when the screen below is displayed:

FRESH: LOW VOLUME SPECIMEN

PLEASE SELECT SAMPLE TESTING OPTION:

1. **DILUTE 1:1 WITH MEDIA**
2. RUN 20 µl SAMPLE–LIMITED REPORT

- Dilute the sample 1:1 with QwikCheck dilution media (see appendix section).
- Follow the instructions in the appendix section of this User Guide: Filling the Testing Capillary with a Normal Volume Sample.
- The system will report accurate results only if the sample has been diluted 1:1 prcisely and the sample is adequate to fill the testing capillary after dilution.

20µl Low Volume Samples

To run a **LOW VOLUME** sample, select option "2" from the screen displayed below:

FRESH: LOW VOLUME SPECIMEN

PLEASE SELECT SAMPLE TESTING OPTION:

1. DILUTE 1:1 WITH MEDIA
2. RUN 20µl SAMPLE-LIMITED REPORT

- Aspirate only 20 µl of sample into the motility section of the capillary following the instructions in the Appendix section of this User Guide: "Filling the SQA Capillary with a Low Volume Samples".

LOW VOLUME SAMPLE

FILL CAPILLARY–20 MICROLITERS
CLEAN AND WIPE CAPILLARY

INSERT CAPILLARY INTO CHAMBER

TEST RESULTS

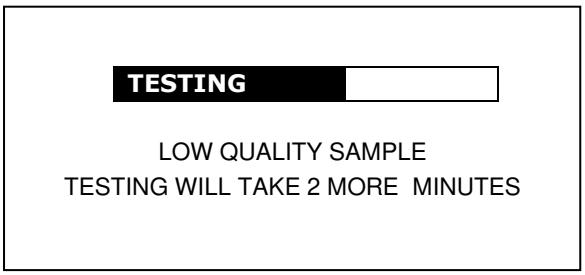
MOTILITY PARAMETERS ONLY

MSC	18.1 M/ml	VELOCITY	3 mic/sec
PMSC	1.0 M/ml	SMI	26

TOTALS PER VOLUME

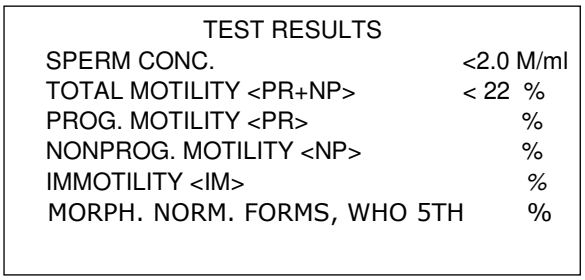
MOT SPERM 18.5M PROG SPERM 6.7M

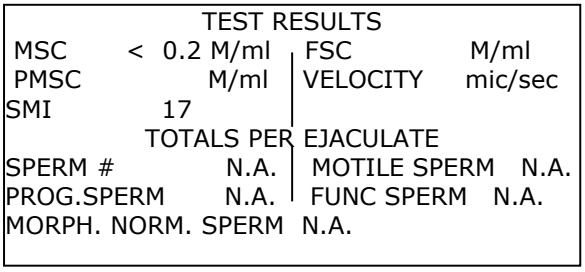
Low Quality Test Results



When a sample is LOW QUALITY, test results may be reported as < or > when parameters fall below the dynamic range of the system. Only the following parameters will be reported: Sperm Concentration, Motility, SMI and Motile Sperm Concentration due to the limited number of cells, very low motility and/or poor morphology.

- Examples of test results reported in this manner are seen in the screens below:





FROZEN, WASHED SAMPLE TESTING

Run FROZEN and WASHED samples in the same manner by selecting SAMPLE TYPE: FROZEN (or WASHED) from the MAIN MENU > TEST NEW PATIENT > ENTER SAMPLE DATA screen. Follow the on-screen instructions.

- FROZEN samples require only 20 microliters of sample and motility parameters only are reported
- WASHED sample can be run with a large or small volume sample (motility parameters only will be report if using 20 microliters)

Printing

- If the QwikCheck was set to automatically print test results on the label maker they will now print.
- If the default was not set, press the PRINT button on the keypad.

Control Set-Up and Testing

SECTION 5: Controls

From the MAIN MENU select: RUN CONTROLS in order to run external quality control samples (CONTROLS). Commercially available stabilized sperm can be run as non-assayed controls. QwikCheck™ beads produced by Medical Electronic Systems are assayed for the QwikCheck GOLD. It is recommended that controls be run daily or based upon laboratory protocols.

Set-Up

Set-Up: Assayed Control: QwikCheck™ Beads

For each new box of controls, system defaults need to be set-up/updated. To do this:

Please note:

When a new control lot is used, the control default settings must be changed prior to initiating a test.

- Go to: MAIN MENU > SERVICE > SET-UP > CONTROLS to view the screen below:

```
SERVICE: SET-UP CONTROLS

SELECT: LATEX BEADS / STABILIZED SPERM
SELECT: LEVEL 1/LEVEL 2/NEGATIVE

PRESS ENTER TO CONTINUE
ESC TO RETURN TO SET-UP MENU
```

- Select the type of control (LATEX BEADS or STABILIZED SPERM)
- Select the level of the control (LEVEL 1, LEVEL 2 or NEGATIVE)
- PRESS: ENTER and the screen below will be displayed:

```
SET-UP: LATEX BEADS LEVEL #1
LOT #:  112233445566778899
EXP DATE: 04/09 MM/YY
TARGET VALUE: 45 +/- 6.3
PRESS ENTER
```

Please note:

For the QwikCheck GOLD to test CONTROLS accurately, the CONTROL defaults must be set-up. If some control information is not available, enter the current date in the EXP Date field and zeros in all other fields.

- From the box/product labeling enter:
  - **LOT#:** number identifying the control media lot.
  - **EXP. DATE:** control expiration date (MM = month, YY = year).
  - **TARGET VALUE and +/- Range:** **M**anufacturer's labeled "Target Value and +/- Range" for the level of the control being set-up.
- PRESS ENTER to save the set-up information.
- Continue to set-up each of the other levels of controls.

To run a non-assayed control, the Target Value and +/- range must be established by the laboratory. Once this is determined, set-up the defaults and test the control in the same way as QwikCheck Beads assayed control.

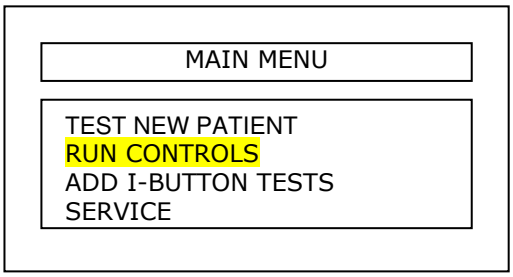
Running Controls on the QwikCheck GOLD

Please note:

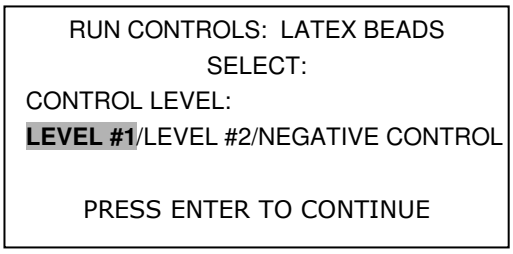
For the QwikCheck GOLD to test CONTROLS accurately, the CONTROL defaults must be set-up. Please refer to the section above to set-up the controls.

CONTROL Testing

- To run controls go to: **MAIN MENU** > **RUN CONTROLS** and press ENTER



- When the screen below is displayed: Select the **CONTROL LEVEL:** #1, #2 or NEGATIVE (LEVEL #3) that is being tested.
- Press **ENTER** to continue.

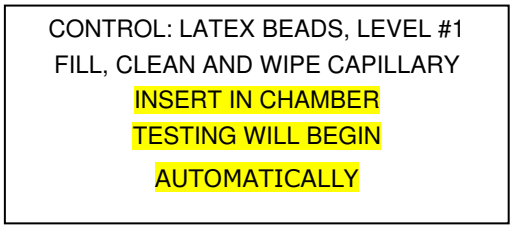


- Fill the testing capillary with the Control media as if you are running a normal volume semen sample.

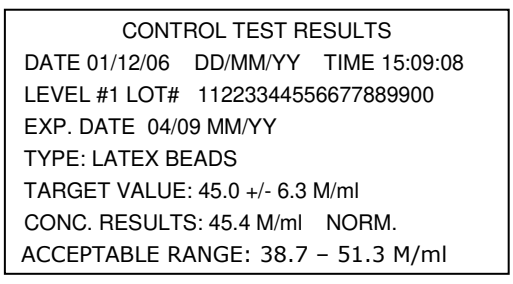
Please note:

Insert the testing capillary with the control media ONLY when prompted by the screen.

- After a screen that asks you to PLEASE WAIT while the system auto-calibrates, the screen below will be displayed:



- Testing will begin automatically.
- Control test results will be displayed on the QwikCheck GOLD screen.
- LOW, HIGH or NORM. will be displayed based on the testing outcome vs. target value and +/- range.
- Test results can be printed by pressing the PRINT button on the keypad.



Electronic Self-Test and Auto Calibration

The QwikCheck automatically runs a series of tests to check calibration settings and the internal operating system. Tests are run when the system is turned on and prior to testing a sample.

Start-up:

- **Stabilization and auto calibration:** Checks system stability and reference ranges. The system sensors are analyzed for several minutes to ensure that the values are within a very narrow acceptable range. Once the system is stable for 30 seconds it will pass stabilization and auto calibration. The system will fail if it is not stable for at least 30 seconds and a warning message will be displayed.
- **System noise:** Measures the electronic noise level of the system to insure effective measurement of electronic signals.
- **Self-test:** The system produces electronic signals that simulate motility and concentration measurements in order to check the performance of the system and verify that the calibration settings are consistent with the factory specifications. The QwikCheck will report failures (see section on error and warning messages) and "freeze" the system if the system is not within the established self-test ranges.

Prior to testing a sample:

- **Auto calibration verification**: Reference values are read again. The electronic parameters of the concentration and motility channels are measured (without a testing capillary).
- **System noise:** Measures the electronic noise level of the system to insure effective measurement of electronic signals. Prior to running a test, the QwikCheck will automatically adjust the noise level thresholds to insure accurate readings.
- **Electronic spikes:** Checks for any measurement points that are out of range electronically. More than three such points will fault the system and a warning message will be displayed.

Instructions for printing the QwikCheck GOLD Self Test parameters to prepare for technical support:

How to print a copy of the SELF TEST DATA:

- Remove the testing capillary from the system.
- When a FAILED SELF TEST message appears select: **MAIN MENU > SERVICE> PRINT SELF TEST DATA AND SETTINGS > SELF TEST DATA.**
- Press **ENTER** after highlighting **SELF TEST DATA** to print a copy of the data.

How to view the system parameters FROM QwikCheck GOLD:

- Go to: **MAIN MENU > SERVICE > SERVICE DATA.** All of the service screens can be viewed by pressing ENTER.

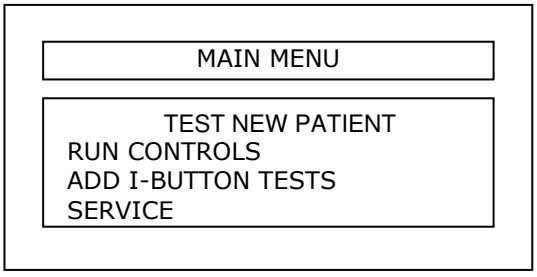
Customer Support/Troubleshooting: To quickly assess if the QwikCheck GOLD is in good calibration, refer to the table and values below. The S/W Ver. 1.00.32 column provides reference ranges for calibration. Enter information from the SELF TEST DATA in the "QwikCheck Value" column to see if the system requires troubleshooting.

#	Parameter	S/W Ver. 1.00.32	QwikCheck Value	Pass	Fail
1.	Ref 1	150 – 350 mV			
2.	LED Cur 1	5 – 25 mA			
3.	Amplitude	50 – 100 mV			
4.	Zero Level	500 - 525			
5.	Ref 2	2500 – 3500 mV			
6.	LED Cur 2	10 – 32 mA			
7.	CONC. 1	0 – 1 M/ml			
8.	CONC. 2	50-150 M/ml			
9.	CONC. 3	300-600 M/ml			
10.	Count (Service Data, Item #12)	26 - 36			

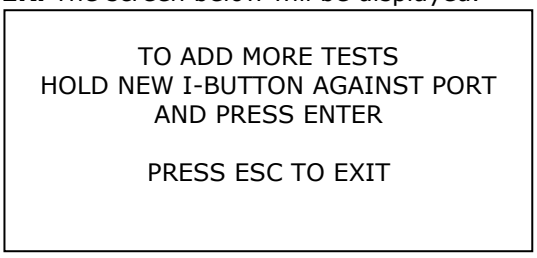
Test Credit Loading

SECTION 6: Add I-Button Tests and Test Credit (TC) Codes

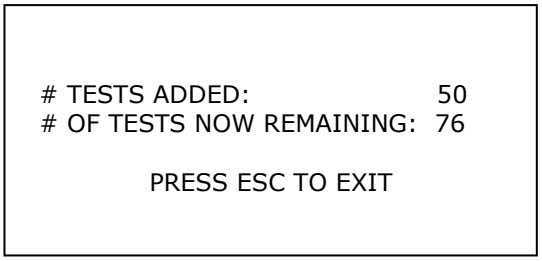
***For users implementing the new **TC-Code internal feature**, please reference the TC-Code Quick Start Guide found in the accessory kit or visit www.testcreditcode.com for instruction on how to load Test Credits onto your device.



- To add I-button tests, go to: **MAIN MENU> ADD I-BUTTON TESTS** and press **ENTER.** The screen below will be displayed.



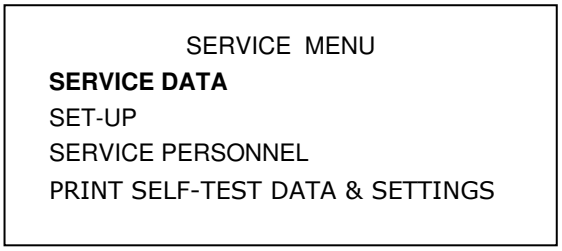
- Follow the on-screen instructions, holding the new i-button firmly against the i-button port located on the side of the QwikCheck GOLD system.



- The screen above will be displayed when the i-button is successfully loaded!

SECTION 7: Service Menu

System set-up, maintenance and troubleshooting can be performed from the SERVICE MENU. To activate this screen, press **SERVICE** in the MAIN MENU.

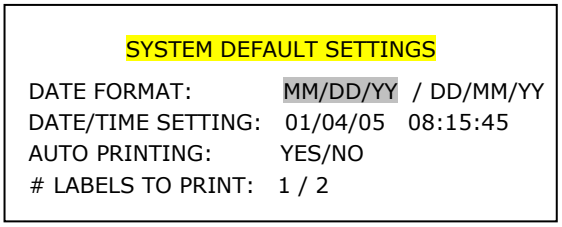


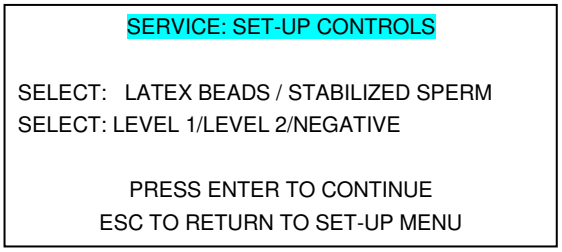
Service Data

Click on this option to view all the SELF TEST, ALGORITHM and SERVICE DATA for the QwikCheck GOLD system.

Set-up

Click on the SET-UP option to set-up all the SYSTEM DEFAULTS (date format; time/date; # labels to print; automatic printing; morphology setting) or to set-up the CONTROL DEFAULTS.



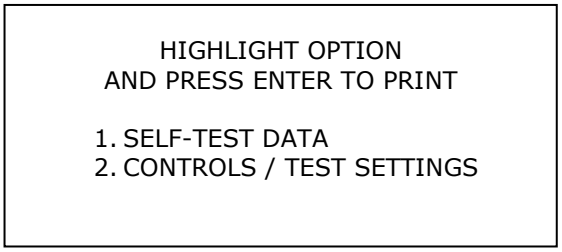


Service Personnel

A **code** is required to access SERVICE PERSONNEL. This option allows a qualified service technician to access calibration and maintenance settings.

Print system Default Settings

The system SELF-TEST DATA and DEFAULT SETTINGS can be printed to the label maker by selecting this option.

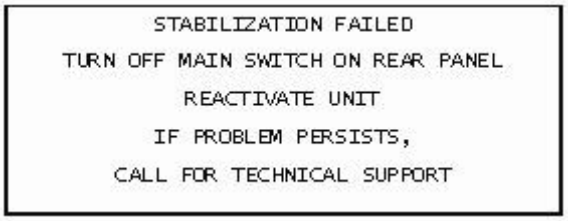


SECTION 8: Error Messages and Warning Messages

General Warning:

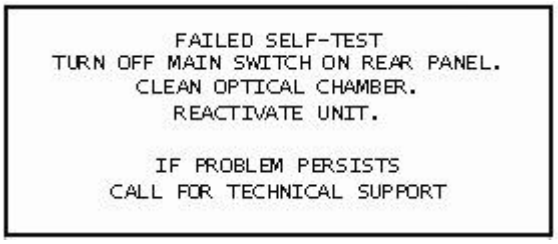
- The QwikCheck Gold should be operated by a professional following the manufacturer's guidelines for optimal results.
- **CAUTION:** There is a risk of explosion or short circuiting the QwikCheck Gold if the battery is replaced by an incorrect type. Replacement batteries MUST be the same type and manufacturer. Dispose of used batteries in accordance with the manufacturer instructions.
- Following the manufacturer's recommended use, the expected life span of the QwikCheck Gold is a minimum of 5 years.

Stabilization Failed:



- Remove any testing capillary from the measurement compartment.
- Operate the device AWAY from electronic noise (cell phones, etc.) and vibrations (centrifuge).
- Clean measurement compartment (refer to Appendix).
- Reboot the QwikCheck system without a testing capillary in the chamber:
  - Turn system **OFF** then back **ON** at the main switch on the rear panel.
  - Press the front panel **ON/OFF** key to begin Auto-Calibration/Stabilization.
- Call technical support if failure recurs.

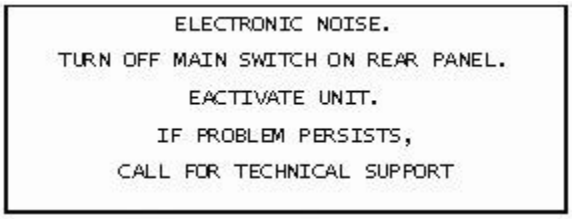
Self-test Failed:



- Ensure there is no testing capillary in the measurement compartment.
- Operate the device AWAY from electronic noise (cell phones, etc.) and vibrations (centrifuge).
- Clean measurement compartment (refer to Appendix).
- Reboot the QwikCheck system without a testing capillary in the chamber:
  - Turn the system **OFF** then back **ON** at the main switch on the rear panel.
  - Press the front panel **ON/OFF** key to begin Auto-Calibration and Stabilization.
- Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the **SERVICE DATA:**

- Press the SERVICE key on the keypad to activate the **SERVICE MENU** screen.
- Select: **PRINT SELF TEST DATA AND DEFAULT SETTINGS>SELF TEST DATA.**
- Press **ENTER**

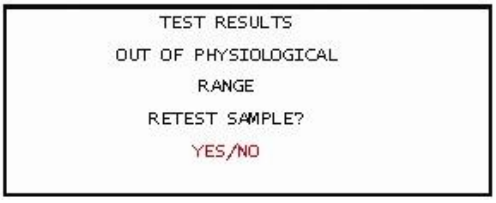
Electronic Noise:



- Ensure there is no testing capillary in the measurement compartment.
- Remove the QwikCheck from sources of electronic noise (cell phones, etc.) and vibrations (centrifuge).
- Clean measurement compartment (refer to Appendix) and after cleaning:
  - Turn the system **OFF** then back **ON** at the main switch on the rear panel.
  - Press the front panel **ON/OFF** key to begin Auto-Calibration and Stabilization.
- From **MAIN** menu: Select **TEST NEW PATIENT** and rerun the test.
- Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the **SERVICE DATA**:
  - Press the SERVICE key on the keypad to activate the **SERVICE MENU** screen.
  - Select: **PRINT SELF TEST DATA AND DEFAULT SETTINGS>SELF TEST DATA.**
  - Press: **ENTER**

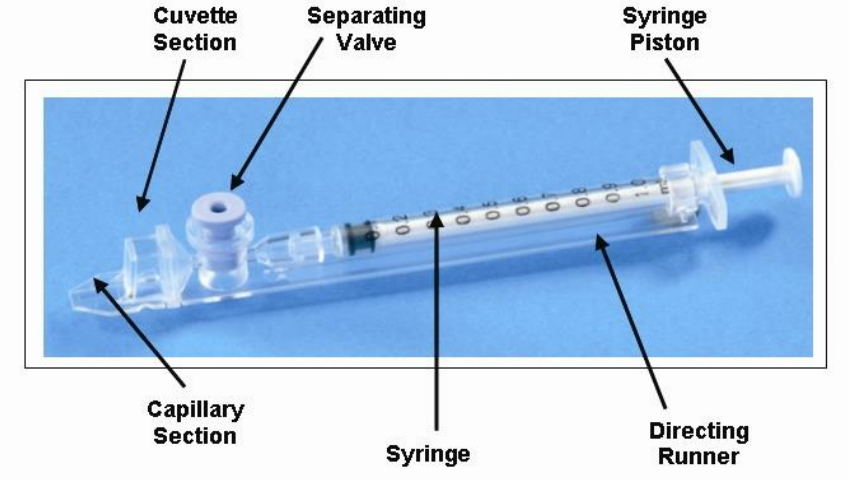
Concentration Out of Range

Testing Semen Sample:



- A message will appear indicating that the tests results for Sperm Conc and/or MSC are beyond the upper limits of the dynamic range established by the manufacturer for testing. This message will appear when:
  - SPERM CONC > 500 M/ml or
  - MSC > 450 M/ml
- Review sample handling technique (see Appendix "Filling the SQA Capillary").
- Re-test the sample using a new SQA capillary. If the message appears again, reboot the system.
- Call for technical assistance if problem persists.

APPENDIX 1: Filling the Testing Capillary with a Normal Volume Sample



Sample size, collection container and preparation:

1. Sample volume should be **at least .5 ml.** If sample volume is less than .5 ml see Appendix 2.
2. Sample container should be **wide-necked and deep enough** to facilitate inserting the capillary into the sample at the bottom of the container.
3. The semen sample must be **completely liquefied and well mixed prior to aspiration**. Gently rotate container to fully mix liquefied specimen.

   WARNING: *Do not shake nor use a pipette to aspirate and dispense specimen in order to mix, otherwise air bubbles will form.*

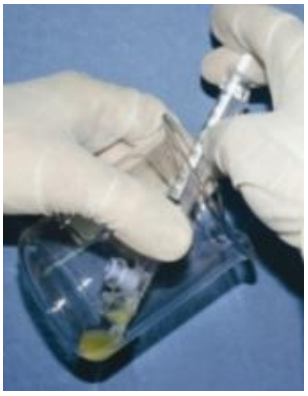


Figure 1

4. **Carefully check that liquefied, fully mixed specimen is free of air bubbles** (or that there is an adequate amount of sample below the air bubbles) before immersing the capillary into the specimen, thus ensuring that no air bubbles will be aspirated into the capillary.

Filling the capillary:

1. **Push the syringe piston in fully**. Place only thin part of the capillary into the bottom of the sample while angling the sample container at about 45 degrees (Figure 1).
2. Placing two fingers below the piston head **pull the piston back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles** (Figure 1). Continue to aspirate the sample until it appears in the Luer adaptor.

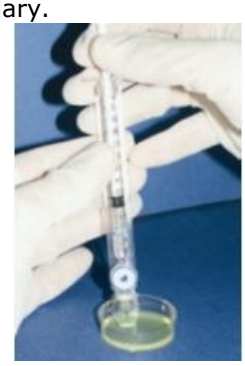


Figure 2

NOTE: *Transferring the sample to a standard "tissue culture dish" (3 cm in diameter/1 cm deep) will allow better visual control when filling the capillary as an intermediate step (see Figure 2).*

3. Holding the capillary in a vertical position (Figure 3), **visually confirm that the sample has completely filled** the thin section (without a meniscus) and the cuvette section and appears in the Luer adaptor. **Tap on the syringe to make sure there are no air bubbles** in the sample. If, after tapping, some air bubbles appear below the Luer adaptor, dip the capillary into the semen sample again and aspirate a small quantity of semen to draw the air bubbles into the syringe.
4. **Quickly (to avoid wicking) and thoroughly wipe the outer surface of the capillary** - both top and bottom (Figure 4) with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to prevent the optical chamber from becoming clogged. Visually confirm that the capillary chambers are still full following the cleaning process. If some of the sample has been depleted (meniscus formed in the thin part of the capillary) fill the capillary part from the cuvette section by slightly pushing in the piston.

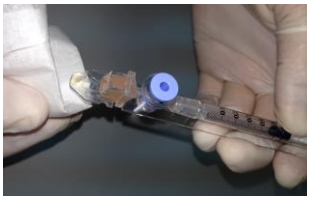


Figure 4 Wipe the tip

Figure 3 Inspect for bubbles

5. Slowly and carefully **push-in the separating valve** until it is level with the plastic (Figure 5). The capillary is now ready to be inserted into the QwikCheck Gold measurement compartment for testing.

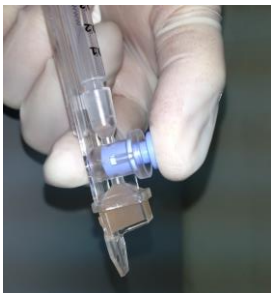
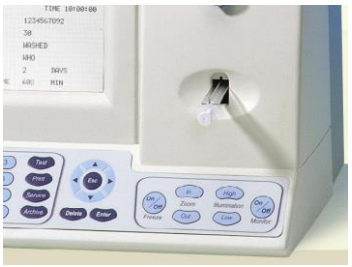


Figure 5 Push-in the piston

Insert the testing capillary into the lower measurement compartment with the blue stopper down. Push it in as far as it will go to ensure that the capillary is properly seated in the compartment.



APPENDIX 2: Filling Testing Capillary with a Low Volume Sample

Sample size, collection container and preparation:

1. A sample as small as 10 microliters can be tested for motility parameters by filling ONLY the thin section of the testing capillary (Figure 1).
2. The semen sample must be **completely liquefied and well mixed prior to aspiration**. Gently rotate the container to fully mix the liquefied specimen. ***WARNING:*** *Do not shake nor use a pipette to aspirate and dispense specimen in order to mix, otherwise air bubbles will form.*
3. **Carefully check that the liquefied, fully mixed specimen is free of air bubbles** (or that there is an adequate amount of sample below the air bubbles) before immersing the capillary into the specimen, thus ensuring that no air bubbles will be aspirated into the capillary.
4. **It is recommended that the sample be withdrawn from a standard "tissue culture dish"** (3 cm in diameter/1 cm deep) to allow for better visual control when filling the capillary.

Figure 1

Figure 2

Filling the capillary:

1. **Push the syringe piston in fully**. Place only the thin part of the capillary into the bottom of the sample (Figure 1).
2. **Pull the piston back slowly** without withdrawing the capillary from the sample. **Fill only the (thin) capillary chamber** with 10 microliters of semen (Figure 1). The exact quantity aspirated can be determined by the gradations on the 1 ml syringe. Aspirate the sample until it just appears in the cuvette part while keeping the tip of the capillary well below the sample level and well below the level of any bubbles covering the liquid. Withdraw the capillary tip from the semen sample and visually inspect the capillary to ensure that the sample has completely filled the thin section (no meniscus).
3. Quickly (to avoid wicking) and **thoroughly wipe the outer surface of the capillary** - both top and bottom with a delicate wipe (Kimwipes, etc.). It is important to remove all semen from the exterior of the capillary in order to prevent the QwikCheck Gold optical chamber from becoming clogged. Visually confirm that the thin chamber of the capillary is still full of semen after completing the cleaning process. If some of the sample has been depleted push-in the piston slightly until the first drop appears on the capillary tip and then fill the capillary again from the sample container.

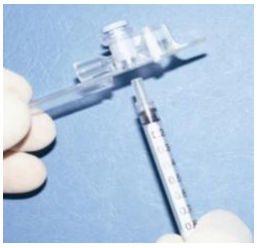
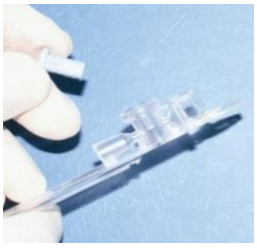


Figure 3

Figure 4



4. The separating valve must now be removed. Detach the entire syringe from the hub (Figure 2) and use the syringe tip to firmly **push-out the separating valve** from the underside of the capillary (Figure 3). Completely detach the separating valve (Figure 4). The capillary is now ready to be inserted into the QwikCheck.
5. **PLEASE NOTE: Test Low Volume samples as soon as the sample is aspirated into the capillary.**

APPENDIX 3: Cleaning the Capillary Compartment

When to clean: DAILY (step 1), WEEKLY (step 2)

- Or if SELF-TEST or any other failure occurs
- Or if System becomes contaminated with semen

Cleaning kit components:

Long cleaning brush

Fibrous material cleaning paddles (single use)

Sponge-tipped drying paddles (single use)

Cleaning fluid (single drop dispenser)

PLEASE NOTE: Cleaning and drying Paddles are for ONE TIME use only!

CLEANING: STEP 1 (DAILY)

- Insert the long brush (bristle side down) into the upper portion of the lower chamber of the SQA in the same manner as a testing capillary (Fig 1 and 2).
- Pull the brush out, applying downward pressure to sweep or 'dust off' the optics (you will feel a 'shelf' in the back/top section of the chamber) – (Fig 2 and 3)
- **Monitor the system's "REF. 2" parameter. It should be between 2800 and 3200 mV if possible.**

CLEANING: STEP 2 (WEEKLY)

1. Use a **Fibrous material** cleaning paddle (fig 4)
   - Moisten with only **ONE** drop of cleaning fluid.
   - Shake off excess fluid.
   - Insert into the measurement compartment fibrous material facing **DOWN ONLY**
   - Move the cleaning capillary in and out three times.
2. Use a sponge-tipped drying paddle into the testing chamber and leave it for 10 – 15 seconds (fig 6).

NOTE: Do not move this drying paddle in and out.

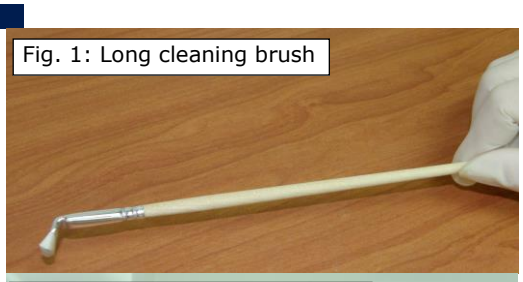


Fig. 1: Long cleaning brush


Fig. 2: Cleaning lower chamber

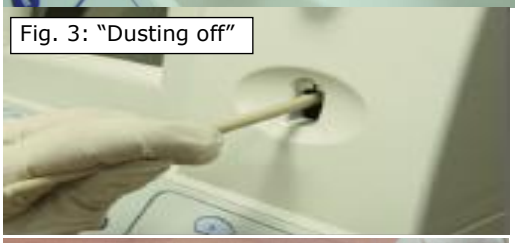


Fig. 3: "Dusting off"


Fig. 4: **FIBROUS** cleaning paddle


Fig. 5: Insertion-**Fibrous material** facing **DOWN**


Fig. 6: Insertion of drying Paddle

APPENDIX 4: Reference Values of Semen Variables

SEMEN PARAMETER	QwikCheck TEST NAME	REFERENCE RANGE*	SOURCE
Sperm Concentration (Count)	SPERM CONC.	≥15 M/ml	WHO 5th manual*
Total Motility (PR+NP)	TOTAL MOTILITY <PR+NP>	≥40 %	WHO 5th manual*
Progressive Motility (PR)	PROG. MOTILITY <PR>	≥32 %	WHO 5th manual*
Non-progressive Motility (NP)	NONPROG. MOTILITY <NP>	-	-
Immotility (IM)	IMMOTILITY <IM>	-	-
Sperm Morphology (normal forms, %)	MORPH. NORM FORMS, WHO 5th	≥4%	WHO 5th manual*
Motile Sperm Concentration	MSC	≥6 M/ml	MES*
Progressively Motile Sperm Concentration	PMSC	≥5 M/ml	MES*
Functional Sperm Concentration	FSC	-	-
Velocity (Curvilinear velocity – VCL)	VELOCITY	≥5 mic./sec.	MES*
Sperm Motility Index	SMI	≥80	MES*
Total Sperm Number	SPERM #	≥39 M	WHO 5th manual*
Total Motile Sperm	MOT. SPERM	≥16 M	MES*
Total Progressively Motile Sperm	PROG. SPERM	≥12 M	MES*
Total Functional Sperm	FUNC. SPERM	-	-
Total Morphologically Normal Sperm	MORPH. NORM. SPERM	≥2 M	MES*

* The ranges established above are based on WHO 5th reference values or MES (for proprietary semen parameters). Each laboratory should establish their own requirements and cut-offs for semen parameters.

APPENDIX 5: Product Performance Data

Abbreviations

TSC: Sperm Concentration (Count)
PMSC: Progressive Motile Sperm Concentration
OD: Optical Density
MSC: Motile Sperm Concentration
Morph Norm Forms: Morphologically Normal Forms
MV: Millivolt

Performance Data Summary

The performance the QwikCheck™ GOLD Sperm Quality Analyzer is the same as the SQA-V (Sperm Quality Analyzer – VISUAL) as they share the same algorithms. Comparison data is available upon request. The following text, tables and graphs demonstrate the performance of the SQA-V algorithms. All values concerning sperm concentration measurements are expressed as 10^6 sperm cells per milliliter (M/ml). Motility and morphology values are expressed as a percent (%). Unless otherwise noted all testing was performed using human donor semen samples.

Calibration:

Each SQA is biologically calibrated against two reference systems at Medical Electronic System's laboratory.

Dynamic Range:

Sample Type	Test Mode	Sperm Conc. M/ml	Motility %	Morph %	MSC M/ml	PMSC M/ml	#Sperm Cells/field
Fresh	Normal	2-400	0-100	0-100	.2-400	0-400	-
Washed	Normal	2-200+	0-100	0-100	.2-200+	0-200+	-
Frozen	Normal	-	-	-	.2-200+	0-200+	-

Precision and Accuracy Established Against a Known Target (Latex beads)

Background: The precision and accuracy of the SQA was compared to a known target value using latex beads.

Latex beads are used as a quality control product to validate the accuracy of sperm counting methods for two known levels of concentration. In accordance with CLIA regulations such a control is used to demonstrate operator proficiency using the microscope and for validation of automated sperm counting methods. The latex beads were run in the SQA in the same manner semen samples are run on the system.

Limitations of method:
Latex beads cannot:

- Measure sperm motility or morphology
- Correct for inaccurate chamber depths or technician errors

Method comparison:
A total of 320 latex bead samples were tested on ten SQA systems (32 samples/SQA). SQA concentration readings were compared to established target values +/- acceptable range.

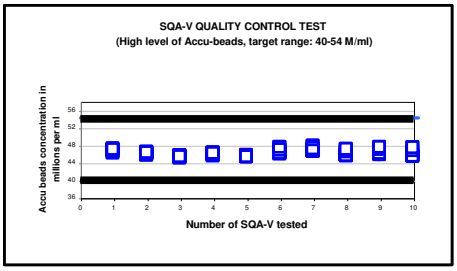
Latex beads established target values +/- ranges (Hemacytometer):

- Vial #1: 47 +/- 7.0 M/ml
- Vial #2: 24 +/- 3.4 M/ml

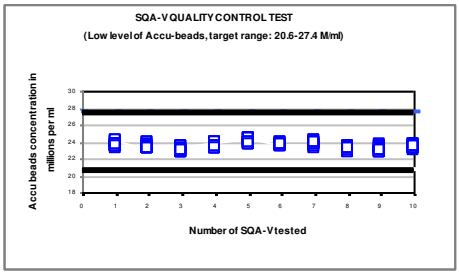
Precision

SYSTEM	Latex-beads	CV, %
Intra-device Variability	**High 47± 7.0 M/ml**	≤ 0.01
	Low 24 ± 3.4 M/ml	≤ 0.01
Inter-device Variability	**High 47± 7.0 M/ml**	≤ 2.00
	Low 24 ± 3.4 M/ml	≤ 2.50

Accuracy: High Level Control



Accuracy: Low Level Control



Precision and accuracy established in clinical trials using human semen samples

Clinical claims:

Specificity
- Concentration: 85%
- Motility: 80%
- Morph. Norm Forms (WHO 3rd): 65%
- Morph. Norm Forms (WHO 4th): 60%
- Morph. Norm Forms (WHO 5th): 90%
- Postvasectomy: 90% of motile cells detected

Sensitivity
- Concentration: 90%
- Motility: 85%
- Morph. Norm Forms (WHO 3rd): 85%
- Morph. Norm Forms (WHO 4th): 65%

Correlation to Manual Method
- Concentration: 0.9
- Motility: 0.85
- Morph. Norm Forms (WHO 3rd): 0.65
- Morph. Norm Forms (WHO 4th): 0.45
- Morph. Norm Forms (WHO 5th): 0.45

Linearity
Linear Sperm Concentration throughout the SQA-V dynamic range of 2M/ml to 400M/ml
- Squared regression coefficient of Dilution Curve $R^2 \geq 0.9$.
- Averaged coefficient of variation CV of measured vs. expected sperm concentration ≤ 20%.

Note: Claims are less than actual correlations noted (see tables 1 and 2).

Background: The SQA-V concentration, motility and morphology readings were compared to standard microscopic results based on WHO 3rd, 4th and 5th standards and MES protocols. Four independent clinical trials were conducted at MES lab, Tel Hashomer andrology dept and Ramat Marpe lab (Israel) and ART laboratory, University Hospital of Nantes (France). A total of >750 human semen samples were analyzed as described below with approximately 350 samples of low quality and tested in the Postvasectomy mode. Among them, 246 semen samples were tested at University Hospital of Nantes.

#Samples	Fresh	Washed	Frozen	High Sensitivity
>750	>300	42	30	>350

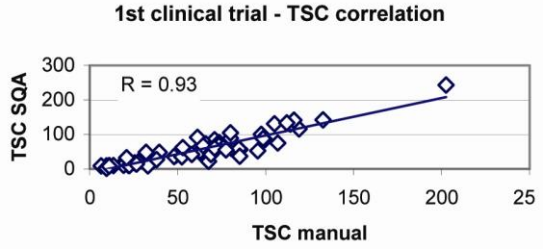
Analytical Specificity:
- To achieve analytical specificity a specific wave length of light which is maximally absorbed by sperm cells and minimally absorbed by other cells and seminal plasma is used.
- Low noise and high electronic resolution hardware components and compensation circuits ensure that analytical specificity is optimized.

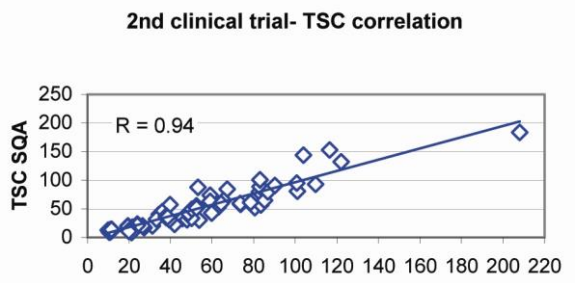
Limitations of clinical specificity:
- Highly viscous samples can only be read accurately with liquefaction (QwikCheck™ Liquefaction Kit used).
- Sample size must be >0.7ml for fully automated tests.
- % Normal Morphology is a parameter derived from the electronic signals of the system by a proprietary algorithm. This is not a direct assessment of the stained smears.
- Results obtained from the use of the SQA-V visualization system may be affected by the subjectivity of the operator.
- Dynamic range limitation as stated above.

Table 1: Sensitivity/Specificity		
SQA-V vs. Microscope	Sensitivity	Specificity
Trial #1:		
Concentration	100%	95%
Motility	97%	85%
Morph Norm Forms (WHO 3rd)	94%	75%
Trial #2:		
Concentration	94%	90%
Motility	87%	90%
Morph Norm Forms (WHO 4th)	69%	70%
Trial #3: High Sensitivity (Postvasectomy - see table #5)		
Motile Sperm Cells	95%	95%
Immotile Sperm Cells	99%	100%
Trial #4 (*ART laboratory, University Hospital of Nantes, France*):		
SQA-V vs. Microscope	Negative Predictive Value	Specificity
Morph Norm Forms (WHO 5th)	92.5	97.9

Table #2: Correlation to Manual Method

Parameters	Correlation Coefficients	
	Trial #1	Trial #2
Sperm Concentration	0.93	0.94
Motility	0.86	0.87
Morphology WHO 3rd	0.66	-
Morphology WHO 4th / 5th	-	0.49*
MSC	-	0.79
* Correlation is low due to narrow dynamic range of this parameter per strict criteria and manual analysis subjectivity.		





Method comparison:

- SQA-V was compared to the microscope based on WHO 3rd (Trial #1), 4th (Trial #2) and WHO 5th (Trial #4) guidelines.
- **Sensitivity and Specificity** were calculated using ROC curves with the cutoffs based on the reference values of WHO 3rd, 4th and 5th guidelines (see Table #1).
- **Correlation** coefficients of the SQA-V results to the manual method are presented in the Table #2.
- **Precision**: Inter-device (Tables #3) and intra-device (Table #4) variations were compared to inter- and intra-operator variability using Coefficients of Variation (CV, %). Duplicate samples were assessed by two methods. The CVs characterizing precision were calculated for multiple semen parameters.
- The **POSTVASECTOMY** test (Trial #3) compared three assessment methods:
  - Microscope (standard slide: X400; 10 fields of view)
  - SQA-V (SQA-V + SQA-V visualization)
  - SQA-V visualization system (see table #2).
- Immotile cells were analyzed by use of the SQA-V visualization system.
- 218 semen specimens contained motile cells and were used as the basis for the Post Vas visualization method comparison (Table #5)

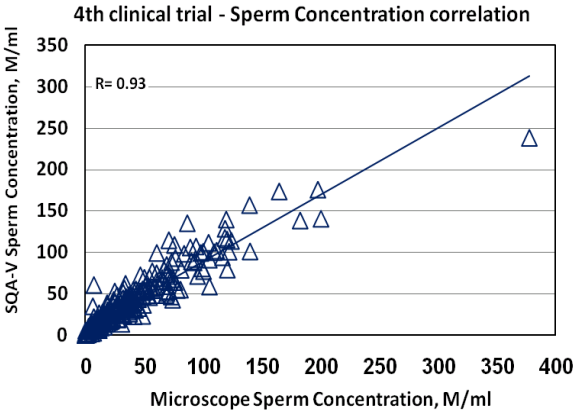
Table #3: Precision: Trial #1 and #2 (n=154)

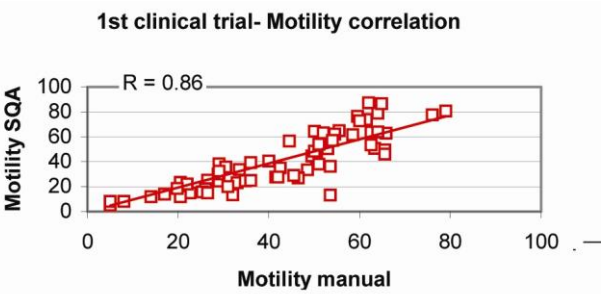
Parameter	Range	Method	
		SQA-V CV%	Microscope CV%
Sperm Concentration	Entire Range	3.1	6.1
	5-40	5.2	5.9
	41-80	2.1	5.5
	>80	2.5	3.2
Motility	Entire Range	5.1	7.2
	10-50	7.6	10.3
	51-55	1.5	3.4
	>55	6.0	4.1

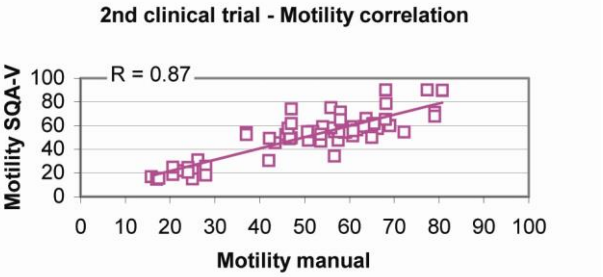
Table #4: Mean Values and Precision: Trial #4 (n=246)

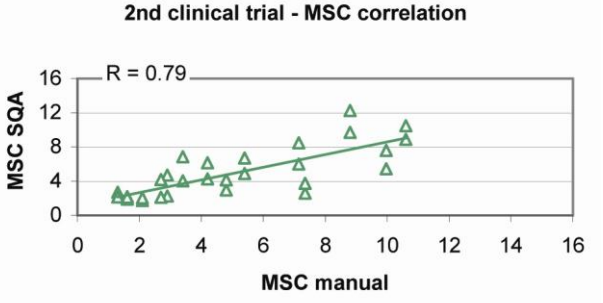
Semen Parameter	Mean			CV, %	
	Op1	Op2	SQA-V	Manual	SQA-V
Sperm Concentration	41.0	40.2	41.4	11.5	3.4
Total Motility	54.7	56.9	54.9	10.7	5.0
PR Motility	37.9	39.0	36.6	13.3	7.5
NP Motility	16.8	17.9	18.4	27.3	6.8
Morphology	7.6	7.6	11.5	27.4	6.5

Note: Op1 - operator 1; Op2 - operator 2









Limitations of method:
Samples were assessed by different operators using a microscope and the SQA-V. Inter-operator subjectivity may have affected the results of the study.

Table #5: Percentage Motile Cells Detected: Trial #3 Postvasectomy mode

Method Comparison of 218 Samples with Motile Cells	# Samples Motile Sperm Detected	% Samples Motile Sperm Detected
SQA-V Automated System and Visualization System	207	95%
Visualization System only	193	89%
Microscope only	161	74%

SQA-V Linearity

Clinical claims:

- Linear Sperm Concentration throughout the SQA-V dynamic range of 2M/ml to 400M/ml:
  - Squared regression coefficient of Dilution Curve R^2 ≥0.9.
  - Averaged coefficient of variation CV of measured vs. expected sperm concentration ≤ 20%.

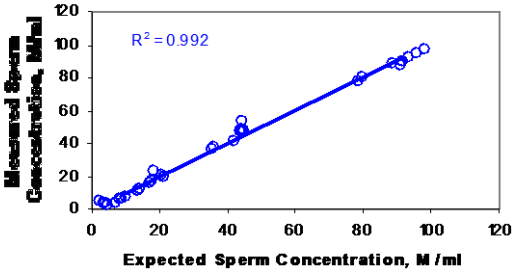
Goal: To demonstrate the ability of the SQA-V to accurately report sperm concentration along the dynamic range of the system using sequentially diluted human semen samples.

Methodology: 4 fresh human semen samples were pooled, divided into two aliquots and centrifuged at 600g for 15 minutes. The seminal plasma was decanted and the pellets were re-suspended in washing media: DPBS & HepesHTF. Sequential dilutions were run in 4 SQA-V systems.

Limitations of method:

- Dilution errors contribute to the accuracy of the linearity test results.
- Sample handling errors such as the introduction of bubbles into the testing capillary can cause inaccurate readings.

SQA-V DILUTION CURVE USING SEMEN DILUTED WITH DPBS & HEPES SOLUTION



Results:

1. Squared regression coefficient R^2 of Dilution Curve (trend line) was found to be 0.992 (note: graph displaying results of four SQA-V's and DPBS and Hepes dilution media).
2. Averaged coefficient of variation CV of measured vs. expected sperm concentration was 10%.

APPENDIX 6: Service Report

SQA SERVICE SUPPORT
Parameter Report

Device number: _____ Software Version: _____ Date: _____

Instruct the user to run a SERVICE report. For the QwikCheck GOLD system go to: **MAIN MENU > PRINT SELF TEST DATA AND DEFAULT SETTINGS>SELF TEST DATA.**

Calibration parameters:

Fill-in the USER REPORT column with the calibration parameters found in the INTERNAL DATA SECTION of the SERVICE DATA REPORT of the QwikCheck GOLD. Contact your local distributor for the initial calibration parameters. These parameters should not have changed.

Parameter	Service Report Item #	User Report	Initial Calibration settings	Comments
CONTR.REF1	#1			
OD AMPLIF.	#13			
MSC AMPLIF	#8			
OD VALUE	#15			
OD CORR	#16			
LB OD AMP	#18			
CONTR. Z.L*	#11			

*CONTR. Z.L. can be adjusted in the field by a MES trained service technician

Algorithm parameters

Fill-in the User Report values for the following algorithm parameters found in the SERVICE DATA REPORT. The QwikCheck algorithm settings are defined and should not have changed.

Parameter	Service Report Item #	User Report	Initial Settings	Comments
MIN.SP.HEIGHT	#2			
MIN.SP.WIDTH	#9			
MAX.SP.WIDTH	#3			
NOISE THRESH	#10			
SMI THRESH	#4			

Self Test Parameters:

Fill-in the QwikCheck SELF TEST PARAMETERS from the SELF TEST printout in V-Sperm:

- From the **MAIN MENU** go to: **SERVICE>PRINT SELF TEST DATA AND DEFAULT SETTINGS>SELF TEST DATA.**
  - Verify that the parameters listed below fall within the established range
  - Highlight the discrepancies and report to MES

Parameter	**S/W Ver. 2.48 Criteria**	**SYSTEM Self-Test Parameters**	
Ref. 1	150 – 350 mV		
LED Current 1	**5 – 20 mA**		Original value
Amplitude	50 – 100 mV		
Count (#12)	26 – 36		
Zero Level	500 – 525		
Ref. 2	2500 – 3500		
LED Current 2	**10 – 32 mA**		Original value
TSC 1 or CONC 1	0 – 1 M/ml		
TSC 2 or CONC 2	50 – 150 M/ml		
TSC 3 or CONC 3	300 – 600 M/ml		

APPENDIX 7: QwikCheck™ TEST Reports

Semen Analysis Report

QwikCheck™ GOLD
SEMEN ANALYSIS REPORT

DEVICE SN#	382
SW VER.	01.XX.XX
TEST DATE	3/12/04 15:26
PATIENT ID	
XXXXXXXXXXXXXXXXXXX	
BIRTH DATE	11/22/51
ABSTINENCE	3 DAYS
ACCESSION #:	
XXXXXXXXXXXXXXXXXXX	
COLLECTED	11/22/04 12:20
RECEIVED	11/22/04 12:25
TYPE	FRESH/WASHED
VOLUME	3.5ml
WBC CONC.	< 1M/ml
PH	7.5

TEST RESULTS

CONC.	32.6M/ml
TOTAL MOTILITY	
<PR+NP>	28%
MOTILITY GRADES:	
PROG. <PR>	16%
NONPROG. <NP>	12%
IMMOT. <IM>	72%
MORPH. NORM. FORMS	
<WHO 5th>	10%
MSC	9.1M/ml
PMSC	6.4 M/ml
FSC	3.2M/ml
VELOCITY	29 mic/sec
SMI	341

TOTALS PER VOLUME

SPERM #	114.1M
MOTILE SPERM	31.9M
PROG. SPERM	22.4M
FUNC. SPERM	11.2M
MORPH. NORM. SPERM	11.4M

SYSTEM DATA

5. 14.08 7. 0.644 12. 456
AW 123456

SYSTEM Default Settings CONTROLS

QwikCheck™ GOLD
SETTINGS

DEVICE SN#	382
SW VER.	01.XX.XX
PRINT DATE 14/01/04	15:33
DATE FORMAT	DD/MM/YY
TIME FORMAT	HH:MM

CONTROLS

LATEX BEADS (or STABILIZED SPERM)	
LEVEL	1
LOT #	5435334656565656
EXP. DATE	05/05
TARGET VALUE	45M/ml
RANGE +/-	5.0M/ml
LEVEL	2
LOT #	75664767676776
EXP. DATE	05/05
TARGET VALUE:	23M/ml
RANGE +/-	2.1M/ml
LEVEL	NEGATIVE
LOT #	546456546565566
EXP. DATE	05/05
TARGET VALUE:	0.0M/ml

Service Data Report

QwikCheck GOLD
Service Report

DEVICE SN#	382
SW VER.	XX.XX.XX
PRINT DATE	01/12/08

SELF-TEST DATA

REF1	230	REF2	2925
LED1	9	LED2	24
AMP	65	CONC1	0.0
SMI	409	CONC2	104.6
ZL	508	CONC3	418.9
AW	14987		

SERVICE DATA

1.	16	7.	0.000	13.	100
2.	5	8.	115	14.	100
3.	150	9.	10	15.	1.70
4.	28	10.	6	16.	100
5.	0.95	11.	130	17.	3
6.	512	12.	31	18.	1000

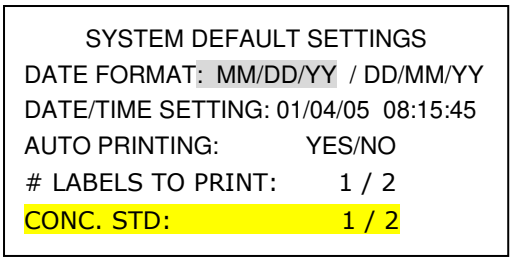
APPENDIX 8: COUNTING CHAMBERS (Concentration Standard Settings)

A number of commercially available counting chambers are used in laboratories for manually counting sperm cells. These chambers vary by depth and one type requires a diluted sample. It has been clinically established that counts vary by approximately 30% depending on the chamber used.

The QwikCheck GOLD HUMAN permits the user to select the type of chamber the laboratory has implemented as a standard for manual semen analysis. Once the concentration standard (CONC. STANDARD) has been selected the QwikCheck GOLD will automatically run semen samples based on that standard.

SQA-V Set-Up:

- From the **MAIN MENU** select: **SERVICE > SET-UP > SYSTEM DEFAULTS** to view the screen below:



- Select a **CONC. (concentration) STD (standard) 1 or 2** based on the options shown in the table below.
- Commercially available counting chambers are divided into two unique groups:
    1. **Standard #1:** 10-20 micron depth and do not require sample dilution.
    2. **Standard #2:** 100 micron depth (haemocytometers) that require sample dilution.

The table below classifies some commercially available chambers:

CHAMBER STANDARD #1	CHAMBER STANDARD #2
Makler	Beurker-Tuek
Micro-Cell	Buerker
Fixed Cover slip disposable chambers	Fuchs-Rosenthal
	Fuchs-Rosenthal (modified)
	Improved Neubauer
	Neubauer
	Malassez
	Thoma
	Thoma Modified

APPENDIX 9: Warranty

Sperm Quality Analyzer

SQA, QwikCheck™ GOLD

Warranty

Medical Electronic Systems ("MES") warrants that the Sperm Quality Analyzer will be free from defects in workmanship and materials for a period of twelve (12) months from date of purchase. During the warranty period, if the device is shown to MES's reasonable satisfaction to be defective, MES shall, at its option, repair such a device without charge for parts or labor. The foregoing remedy shall be purchaser's sole and exclusive remedy under this warranty. In the event (i) purchaser makes any modifications or alterations to the SQA /QwikCheck GOLD or (ii) the SQA/QwikCheck GOLD is used, operated, opened or serviced other than as directed by MES or is damaged as a result of use, careless transportation (not in its original box, or within the allowed temperature range, operation or servicing other than as directed by MES, the foregoing warranties shall be void and of no further force or effect. EXCEPT FOR THE FOREGOING WARRANTIES, THE PRODUCTS ARE SOLD AS-IS AND WITHOUT ANY OTHER WARRANTY OF ANY NATURE WHATSOEVER. MES HAS NOT MADE AND DOES NOT MAKE ANY OTHER REPRESENTATION, WARRANTY, GUARANTY, OR COVENANT, EXPRESS OR IMPLIED, WITH RESPECT TO THE DESIGN, CONDITION, DURABILITY, SUITABILITY, FITNESS FOR USE, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY OF THE SQA IN ANY RESPECT. UNDER NO CIRCUMSTANCES AND IN NO EVENT, WHETHER AS A RESULT OF BREACH OF CONTRACT OR WARRANTY, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, INCLUDING BUT NOT LIMITED TO INACCURATE RESULTS OR OPERATOR ERROR, SHALL MES BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL MES'S LIABILITY WITH RESPECT TO THE PRODUCT EXCEED THE PURCHASE PRICE FOR SUCH PRODUCT.

Extended service contracts are available for purchase.
Please contact the dealer or supplier for information.

Serial Number:_____ Date Purchased:_____
Dealer:_____ Dealer Phone#: _____
Purchaser:_____ Purchaser Phone #:_____

Appendix 10: Regulatory Information

European Authorized Representative:
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17-15 Komazawa 1-chome Setagaya-ku
Tokyo 1540012
JAPAN

Manufacturer:
Medical Electronic Systems, Ltd. 20 Alon Hatavor St., Zone 6, P.O. Box 3017, Caesarea Ind. Park 3088900, Israel

Catalog # F-A-00767-00